ANDA 75-093

August 10, 1999

IMPAX Pharmaceuticals, Inc.
Attention: Mark C. Shaw
30831 Huntwood Avenue
Haywood, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application dated March 13, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Pentoxifylline Extended-release Tablets, 400 mg.

Reference is also made to your amendments dated August 26, 1997; January 29, February 21, June 18, and December 28, 1998; and March 10, April 1, May 7, May 25, July 22, and July 29, 1999.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Pentoxifylline Extended-release Tablets, 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Trental® Tablets, 400 mg, of Hoechst Marion Roussel).

Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application. The "interim" dissolution test(s) and tolerances state that the dissolution testing will be conducted in 900 mL of deionized water at 37^0C, using USP XXIII Apparatus II (paddle), at 75 rpm. The test product should meet the following “interim” dissolution specifications:

Time	Specification
1 hour	
2 hours	
4 hours	
6 hours	
20 hours	

The "interim" dissolution test(s) and tolerances should be finalized by submitting a supplemental application containing dissolution data for the first three production size batches. The supplemental application should be submitted under 21 CFR 314.70(c)(1) when there are no revisions to the “interim” specifications or when the final specifications are tighter than the “interim” specifications. In all other instances the supplement should be submitted under 21 CFR 314.70(b)(2)(ii).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies that may be identified during the methods validation process.

Sincerely yours,

Douglas L. Sporn
Director

Office of Generic Drugs
Center for Drug Evaluation and Research